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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,238	05/08/2000	CORNELIA BERGHOF	2727-102	8813

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EXAMINER	
SITTON, JEHANNE SOUAYA	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/508,238	BERGHOF ET AL.	
	Examiner	Art Unit	
	Jehanne E Souaya	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *18 July 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Currently, claims 46-64 are pending in the instant application. Claims 1-45 have been canceled. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are newly applied. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Grounds of Objection and Rejection

Claim Objections

3. Claim 60 is objected to for being dependent on a rejected claim.

Claim Rejections - 35 USC § 112

4. Claims 47-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER Rejection.

The claims have been amended to recite minimum lengths of nucleic acids which do not find specific support in the specification. The claims recite minimums of 16, 17, 18, 19, and 20

contiguous nucleotides with no upper length limitation. The specification, however, only provides support nucleotides that are from "10 to 250" nucleotides long, or from "15 to 30" nucleotides long. The specification does not appear to specifically support nucleotides comprising "16" or "17" or "18" or "19" or "20" contiguous nucleotides.

5. Claims 46-59 and 61-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims recite "comprising" language (claims 46-59 and 61-64). Such claims encompass sequences on either side of the minimum length from the disclosed SEQ ID NOS: or undisclosed sequences, recited in the claims. Such sequences encompass sequences from the complete 5s-23s intergenic sequence of any species of Pseudomonas, as well as sequences from other sources. For example, claims 46-51, and the products in claims 56-57, read on Accession number AC122145, which is a sequence from chromosome 10 of *Oryza sativa* which "comprises" nucleotides 72-91 of instantly disclosed SEQ ID NO: 1. This sequence was neither taught nor described by the specification. Claims 46, 47, and products in claims 56 and 57 also read on a human EST clone, accession number AA535879, which "comprises" nucleotides 1-16 of instantly disclosed SEQ ID NO: 3 (which is within SEQ ID NO: 1). The specification has only taught a single sequence (SEQ ID NO: 1) and sequences within it (SEQ ID NOS: 3-5), from Pseudomonas aeruginosa. However, the specification has not taught that SEQ ID NO: 1 is the

full-length 23s-5s intergenic spacer for Pseudomonas aeruginosa. As such, the sequences read on full-length sequences not taught or described by the specification. The response asserts that SEQ ID NO: 1 "corresponds" to the full-length 23s/5s intergenic region of Pseudomonas aeruginosa. This argument has been thoroughly reviewed but was found unpersuasive, as it is unclear if the use of the term "corresponds" is meant to indicate that it actually *is* the full length intergenic spacer, or if it is a sequence from *within* it (and can be used to detect it). Secondly, the attorney's arguments are not considered to be persuasive in the absence of a sworn declaration attesting to what the sequence of SEQ ID NO: 1 is. The reason for requiring evidence in declaration or affidavit form is to obtain the assurances that any statements or representations made are correct as provided by 35 U.S.C. 25 and 18, U.S.C. 1001. In *Ex parte Gray* (10 USPQ2d 1923) the Courts held that conclusory statements made in publications could not substitute for declaratory evidence filed under 37 CFR 1.132. Consequently, a Declaration filed under 37 CFR 1.132 sworn by at least one of the instant inventors which explains the what the sequence of SEQ ID NO: 1 *is*, is required.

In addition, regardless of whether SEQ ID NO: 1 is the full length 23s/5s intergenic spacer from Pseudomonas aeruginosa, it is clear from the claimed recitation, that the claims are drawn to the 23s/5s intergenic spacer and sequences within it, from any species of Pseudomonas, as well as sequences from any source (specifically, claims 46-54). However, the disclosure of a single sequence is not representative of the large number of intergenic spacer sequences encompassed by the broadly claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was

in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of sequences consisting of SEQ ID NOS: 1 and 3-5, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

It is noted that kits containing, as well as methods of using, sequences which do not satisfy the written description requirement also lack written description.

6. Claims 58-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "a method for detecting Pseudomonas..." however the final process step only recites a contacting step. Therefore, it is unclear if the claims are drawn to detecting Pseudomonas, or to contacting a sample with a nucleic acid.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 46, 47, 52, 53, and 55 are rejected under 35 U.S.C. 102(a) as being anticipated by EST accession number AA535879 (August 21, 1997).

The accession number teaches a cDNA sequence that comprises nucleotides 1-16 of SEQ ID NO: 3, which is found within instantly claimed SEQ ID NO: 1. As the accession number discloses that the sequence is a cDNA clone, such inherently teaches that the sequence also exists as RNA. With regard to claim 55, the sequence inherently contains a binding site for a moiety, such as a ^{32}P isotope, which would produce a detectable signal to detect hybridization with a sequence consisting of nucleotides 1-16 of SEQ ID NO: 3. As such a sequence is found within Pseudomonas DNA, the teachings of the accession number anticipate claim 55 as well.

8. Claims 58 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Mantynen et al.

Mantynen teaches contacting a sample with primer 2 (page 136, col 2) wherein nucleotides 13-24 of primer 2 are identical to nucleotides 11-22 of instantly disclosed SEQ ID NO: 5 which is within instantly disclosed SEQ ID NO: 1. As claim 58 lacks a positive step relating back to the preamble, the claim encompasses a method comprising a step of contacting a sample with a nucleic acid that comprises 10 contiguous nucleotides of SEQ ID NO: 1, which is taught by Mantynen.

Claim Rejections - 35 USC § 103

9. Claims 56 and 57 arte rejected under 35 U.S.C. 103(a) as being unpatentable over Mantynen in view Ahern.

Mantynen teaches a sequence: primer 2 (page 136, col 2), wherein nucleotides 13-24 of primer 2 are identical to nucleotides 11-22 of instantly disclosed SEQ ID NO: 5 which is within instantly disclosed SEQ ID NO: 1. Primer 2 taught by Mantynen reads on the polynucleotides of claims 56 and 57. Although Mantynen does not teach packaging the primers used in the method of Mantynen in kit format, Ahern specifically teaches that more researchers are buying premade reagents and kits because they are convenient and save time (see p. 4, 2nd para), and that putting products in kit format offer scientists the opportunity to better manage their time (see p. 4, first para). Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to package the sequences of Mantynen in kit format for the purposes of providing probes and primers in convenient format to make detecting the sequences

of Mantynen easier to perform. It is noted that the use for the kits of claims 56 and 57 carry no patentable weight.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. No claims are allowable. Claim 60 would be allowable if written in independent form, containing a positive process step relating back to the preamble.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (703) 308-6565. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

Note: The examiner's name has changed from Jehanne Souaya to Jehanne Sitton. All future correspondence to the examiner should reflect the change in name. It is also noted that after January 12, 2004, the examiner will be located at the new USPTO campus and will be reachable at telephone number (571) 272-0752.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Sitton

Jehanne (Souaya) Sitton
Primary Examiner
Art Unit 1634
11/17/03